

510 (K) Summary
SmartWire Pressure Guide Wire

KO70487

Dave Prepared: February 8, 2007

Submitted by: Volcano Corporation
2870 Kilgore Rd.
Rancho Cordova, CA 95670

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MAR 16 2007

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Device Name: SmartWire® Pressure Guide Wire

Classification name:	<u>Class</u>
➤ 870.1330 Catheter guide wire	II
➤ 870.2870 Catheter tip pressure transducer	II

Predicate Device:

The Volcano Corporation SmartWire® Pressure Guide Wire is substantially equivalent to the predicate device, Volcano SmartWire® Pressure Guide Wire cleared under K021219 on May 17, 2002.

Device Description:

The SmartWire II is a steerable guide wire with a pressure transducer mounted 3 cm proximal to the tip. The SmartWire measures pressure when used with the SmartMap®, WaveMap®, and ComboMap® Instruments. The SmartWire II is available in a diameter of 0.014" (0.36 mm), lengths of 185 cm and 300 cm, and different tip flexibilities. The SmartWire II is packaged preconnected to the connector with a torque device to facilitate navigation through vasculature.

Intended Use:

The SmartWire® Pressure Guide Wire is indicated for use to measure pressure in blood vessels including both coronary and peripheral vessels, during diagnostic angiography

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and/or any interventional procedures. Blood pressure measurements provide homodynamic information for the diagnosis and treatment of blood vessel disease.

Device Technological Characteristics and Comparison to Predicate Device:

The Volcano Corporation SmartWire® Pressure Guide Wire is substantially equivalent to the predicate device, Volcano SmartWire® Pressure Guide Wire cleared under K021219 on May 17, 2002. Modifications include changes to the material used in the Guide Wire.

The modified SmartWire® Pressure Guide Wire uses the same fundamental scientific technology and has the same intended use as that of the predicate device.

Performance Data:

Applicable testing was performed in accordance with the Design Verification Plan including a Risk Analysis addressing the impact of modifications to the device and components. The test results indicate the revised product is comparable to the predicate device. The new material was tested for biocompatibility according to ISO 10993-1 and the results met the predetermined acceptance criteria.

Conclusion:

The Volcano SmartWire Pressure Guide Wire has the same performance specifications, fundamental scientific technology and intended use as that of the predicate device, Volcano SmartWire Pressure Guide Wire cleared under K021219 on May 17, 2002.

Modifications to the device do not raise any new questions regarding safety or efficacy. The performance data and a declaration of conformity with design controls support a determination of continuing substantial equivalence of the modified device to the predicate device.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Volcano Corporation
c/o Ms. Cynthia Van Duker
Regulatory Affairs Manager
2870 Kilgore Road
Ranch Cordova, CA 95670

MAR 16 2007

Re: K070487

Trade Name: SmartWire™ Pressure Guide Wire

Regulation Number: 21 CFR 870.1330 and 870.2870

Regulation Name: Catheter Guide Wire and Catheter Tip Pressure Transducer

Regulatory Class: Class II (two)

Product Code: DXQ and DXO

Dated: February 8, 2007

Received: February 20, 2007

Dear Ms. Van Duker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Page 2 – Ms. Cynthia Van Duker

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): K070487

Device Name: SmartWire Pressure Guide Wire

Indications for Use:

The SmartWire Pressure Guide Wire is indicated for use to measure pressure in blood vessels including both coronary and peripheral vessels, during diagnostic angiography and/or any interventional procedures. Blood pressure measurements provide hemodynamic information for the diagnosis and treatment of blood vessel disease.

The intended use and indications for use of the modified device as described in its labeling have not changed. The fundamental scientific technology of the modified device has not changed.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription
Use X

OR

Over-the-Counter
Use _____

(Per 21 CFR 801.19)

B. J. Zimmerman
(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K070487